UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: February 3, 2021

SUBJECT: Efficacy Review for Condor 2,
EPA Reg. No. 4091-21
DP Barcode: 459620
E-submission No. 55785

FROM: Kristen Willis, Chief
Product Science Branch
Antimicrobials Division (7510P)

TO: Eric Miederhoff, PM 31/Perri Moeller
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: W.M. Barr & Company, Inc.

Formulation from the Label:

Active Ingredient(s)	% by wt.
Alkyl* dimethyl benzyl ammonium chloride (*50% C14, 40% C12, 10% C16)	0.200%
Octyl decyl dimethyl ammonium chloride	0.150%
Didecyl dimethyl ammonium chloride	0.075%
Dioctyl dimethyl ammonium chloride	0.075%
Other Ingredients	99.500%
Total	100.000%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: Label Amendment

Currently registered efficacy claim(s): Disinfectant (bactericidal, virucidal, fungicidal), non-food contact sanitizer, 24-hour residual sanitizer

Requested action(s): Add residual virucidal claims.

Documents considered in this review:

- Cover letter from applicant to EPA dated 10/2/2020
- Proposed label Version 122120 PRIA AMEND
- Data Matrix (EPA Form 8570-35) dated 102/1/2020
- One efficacy study (MRID 51300901)
- Confidential Statement of Formula (EPA Form 8670-4) dated 1/14/2020

II PROPOSED DIRECTIONS FOR USE

Residual Viral activity

To kill 99.9% of viruses for 24 hours: Preclean heavily soiled surfaces. Hold container 6”-8” from surface and spray until thoroughly wet. For use on hard, nonporous nonfood contact surfaces. Allow to air dry without wiping. Reapply if surface is scrubbed. [Kills 99.9% of viruses [within 5 minutes of contamination event [touch] for 24 hours]].

III STUDY SUMMARIES

1.	**MRID**	51300901
Study Objective		Residual Activity of Dried Chemical Residue
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest A29779-1
Experimental Start Date		05/27/20 **Study Completion Date:** 10/2/20
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Influenza A (H1 N1) virus, ATCC VR-1469, Strain A/PR/8/34
Indicator Cell Culture		MDCK canine kidney (ATCC CCL-34)
Test Method		Residual Self Sanitizer Modified for Virus
Application Method		The sprayer was set to "mist" and primed with at least 4 pumps to ensure even flow, prior to treatment. The test substance was applied to replicate carriers by spraying with 3 pumps, at a distance of approximately 6 to 8 inches above the carrier surface, at approximately a 45° angle. After treatment, the test substance on the carriers was allowed to dry at approximately 20-23°C (22.10°C) targeting 45-48% (46.78%) relative humidity, in a humidity controlled chamber for up to 1 hour (55 minutes) such that the inoculation of carriers began no longer than 1 hour after treatment of the carrier. The inoculation of the carriers began less than 1 hour after treatment of the carriers. The initial drying was on a level surface in the

		environmental chamber. The test substance was completely dried on the test carriers prior to initiating the Wear Cycles (additional detail below).
Test Substance Preparation	**Name/ID**	Condor 2
	Lots ☒ **1** ☐ **2** ☐ **3**	KK007-72 (0.447% quaternary ammonia),
	Preparation	Tested concentration: LCL Tested Dilution: RTU Diluent: N/A
Soil load		5% fetal bovine serum
Carrier type, # per lot		Glass panel scored into (4) 1" x 1" carriers
Test conditions		Contact time: 4.5 minutes Temperature: 21.5°C Relative humidity: 34.79%
Neutralizer		None. See below for explanation.
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		The study was not run under GLP. No deviations from GLP were noted. Additional details on the wear and reinoculation cycles: Initial Inoculation A 10 µL aliquot of the in initial inoculation virus was spread to within 1 /8 inch of the surface edge of each test and control carrier with a bent needle. Test carriers and abrasion control carriers underwent a wear and re-inoculation regimen including a series of 12 wear cycles and 11 re-inoculation cycles. All abrasions were conducted at room temperature (19.0-20.0°C) and relative humidity of 40-50%. Between abrasions, the carriers were returned to a humidity - controlled chamber uncovered at approximately 20-23°C (22.0-22.2°C) and 45-48% (46%) relative humidity. The weights of the fully assembled abrasion boats were 1084±1.0g. The abrasion tester was set to a speed of 2.25 to 2.5 (actual speed -2.4) for a total surface contact time of approximately 8-10 seconds (8.94-9.14 seconds), for one complete abrasion cycle. Each abrasion cycle equaled four passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. After each complete set of abrasions were conducted (all control and test carriers abraded), the carriers were allowed to sit undisturbed for ~15 minutes. Control and test carriers were then re-inoculated with 10 µL of re-inoculation virus, spread with a bent needle one carrier at a time, within 1/8 inch of the surface edge and returned to the humidity-controlled chamber uncovered at

	approximately, until completely dry, prior to initiation of the next set of abrasions. EPA asked for clarification on the neutralizer that was used and received the following response from the authorized agent on 1/18/2021. To address the question from efficacy: The report on page 9 under Determination of Residual Activity states the carriers were transferred to growth medium and further diluted in growth medium. These are then added to the host cells. On page 6, the Test Medium is defined. We can provided the raw data if this needs to be verified. Since in this study design we are recovering virus from on top of a dried film of test material, the need for neutralizer is greatly reduced. The product does not need to come off to fully recover the survivors.

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results*	Average Dried Virus Control (Log_{10} $TCID_{50}$/carrier)		Average Abrasion Carrier Control (Log_{10} $TCID_{50}$/carrier)
4.5 minutes, RTU spray, 5% fetal bovine serum, Lot *KK007-72*						
51300901	Influenza A (H1 N1) virus, ATCC VR-1469, Strain A/PR/8/34	10^{-1} to 10^{-2} dilution*	Cytotoxicity	**Day 1**	$10^{5.39}$	$10^{5.71}$
		10^{-3} to 10^{-8} dilution*	Complete inactivation	**Day 2**	$10^{4.5}$	
		Average $TCID_{50}$/carrier	$\leq 10^{1.5}$	**Day 3**	$10^{4.64}$	
		Average Log_{10} Reduction	4.21			

*Representative of all 4 replicates

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51300901	Residual viral activity	Hard non-porous surface	Spray 6-8 in. from surface; Ready-to-Use	4.5 minutes	5% fetal bovine serum	N/A	• Influenza A (H1 N1) virus, ATCC VR-1469, Strain A/PR/8/34	**Yes**

VI LABEL COMMENTS

Label Date/Identification Number: Version 122120 PRIA AMEND

1. The proposed label claim that the product, Condor 2, when applied as a ready to use spray, has residual viral activity against Influenza A (H1 N1) virus on hard, nonporous nonfood contact surfaces within 5 minutes of contamination when allowed to air dry for up to 24 hours.

   This claim is **acceptable** as it is supported by the submitted data.

2. Make the following changes to the proposed label:

   a. On page 11 under Residual Activity Claims,
      i. To ensure proper use and avoid confusion for the end user (i.e., disinfectant vs residual virus claims), all residual virus claims should include the virus tested in the claim text rather than with the qualifier "9". For example, "Keeps killing virus[9] on treated surfaces [even after multiple touches][for 24 hours]" should be revised to "Keeps killing influenza A H1N1 virus on treated surfaces [even after multiple touches][for 24 hours]".
      ii. Qualify each instance of "surface/s" to add "hard, nonporous" as a descriptor to accurately reflect the intended type of surfaces for treatment. Alternatively include this qualifier in a footnote.
      iii. Revise/qualify the following claims to specify that the product protects the surface rather than providing protection to the end user.
         - "Protects against bacteria and viruses[9] between cleanings for up to 24 hours"
         - "24 Hour [Full day] surface protection against bacteria and viruses[9]"
         - "Touch-proof protection for 24 hours against bacteria and viruses[9]"
         - "Actively defends for 24 hours against bacteria and viruses[9]"
         - "[Daily] [Full day] protection from 99.9% of bacteria and viruses[9]"
         - "Active protection for a full 24 hours against bacteria and viruses[9]"
         - "Protection that lasts 24 hours, even after multiple touches against bacteria and viruses[9]"
         - "All-day protection against bacteria and viruses[9]"
      iv. Remove brackets from treated surfaces on the following claim. That qualifier is not optional:
         i. Protects [treated [household] [commercial] [industrial] [institutional] [business] [professional] surfaces] from bacteria and viruses[9]"